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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/934,250	08/21/2001	Wenbin Dang	GPT-029.01	6514
29755	7590	08/18/2006	EXAMINER	
FOLEY HOAG, LLP PATENT GROUP (w/GPT) 155 SEAPORT BOULEVARD BOSTON, MA 02110-2600			HUI, SAN MING R	
			ART UNIT	PAPER NUMBER
			1617	

DATE MAILED: 08/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/934,250

Applicant(s)

DANG ET AL.

Examiner

San-ming Hui

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-18,22-25,30-41 and 57 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18,22-25,30-41 and 57 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### **DETAILED ACTION**

Applicant's amendments filed May 22, 2006 have been entered. Claim 57 has been added.

The claims are now directed to the pharmaceutical composition "consisting essentially of" the biocompatible oil and the salt of caine analgesics or analgesic.

The outstanding rejection under 35 USC 102(b) is withdrawn in view of the amendments filed May 22, 2006 as the claims are directed to the inorganic salt of caine analgesic.

The outstanding rejections under 35 USC 103(a) are withdrawn in view of the amendments filed May 22, 2006 as the claims are directed to a composition consisting essentially of an inorganic salt of analgesic agent. The cited prior arts teach compositions containing lidocaine with various agents.

Claims 1-18, 22-25, 30-41, and 57 are pending.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,879,705 ('705).

'705 teaches a composition comprising morphine sulfate (more than 2%), vegetable oil and polyethylene glycol. Examiner notes that the composition contains no more than 5% of solvent (See col. 7, TABLE 1, Example 5 and 7).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-18, 22-25, 30-41 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katzung in view of Lostritto and Remington Pharmaceutical Sciences, 18<sup>th</sup> ed., 1990, pages 294-298 and 1300-1304. Katzung and Lostritto are references of record.

Katzung teaches various dosage of lidocaine for parenteral use as 150-200mg as loading dose or 2-4mg/min as parenteral dosage (see page 220, last paragraph brading

page 221). Katzung teaches various dosage of lidocaine for parenteral use as 0.5, 1, 1.5, 2, 4, 10, 20% (See page 402).

Katzung does not expressly teach the use of biocompatible oil such as sesame oil in the parenteral composition. Katzung does not expressly teach the amount of sesame oil used or the amount of lidocaine hydrochloride. Katzung also does not expressly teach the particle size of the particles in the composition.

Lostritto teaches lidocaine can be formulated into parenteral solution in which sesame oil is one of the suitable solvent and that sesame oil is compatible with lidocaine hydrochloride.

Remington teaches sesame oil, corn oil, cottonseed oil are all well-known conventional diluent for injection (See page 1303). Remington also teaches the particle size in suspension or emulsion is typically more than  $2\mu\text{m}$  to about  $100\mu\text{m}$  (See page 295, col. 2 regard to the Stoke's Law and page 298, in emulsion Section).

It would have been obvious to one of ordinary skill in the art at the time of invention to adjust to the amount of lidocaine hydrochloride and oil to the herein claimed amount and weight ratio. It would have been obvious to one of ordinary skill in the art at the time of invention to adjust the particle size for optimizing the flocculation of the suspension or emulsion.

One of ordinary skill in the art would have been motivated to the amount of lidocaine hydrochloride and oil to the herein claimed amount and weight ratio since optimization of result effect parameters (e.g., dosage range, dosing regimens) is obvious as being within the skill of the artisan. Furthermore, knowing that lidocaine

hydrochloride is compatible with sesame oil and sesame oil is a well-known commonly used vehicle for injection, employing sesame oil as the carrier in the lidocaine composition would be obvious. As anyone of ordinary skill in the art will appreciate, preferred dosages are merely exemplary and serve as useful guideposts for the physician. There are, however, many reasons for varying dosages, including by orders of magnitude; for instance, an extremely heavy patient or one having an unusually severe infection would require a correspondingly higher dosage. Furthermore, it is routine during animal and clinical studies to dramatically vary dosage to obtain data on parameters such as toxicity.

One of ordinary skill in the art would have been motivated to adjust the particle size for optimizing the flocculation of the suspension or emulsion since the adjustment of particle size would optimize the sediment rate and flocculation/deflocculation of the suspension and the stability of emulsion. Such optimization is considered obvious as being within the purview of skilled artisan.

### ***Response to Arguments***

Applicant's arguments with respect to claims 1-18, 22-25, 30-41 and 57 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1617

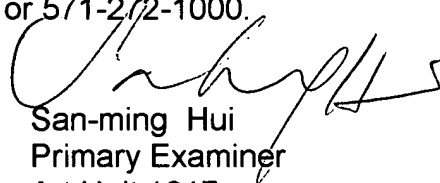
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1617

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



San-ming Hui  
Primary Examiner  
Art Unit 1617